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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,866	07/28/2003	Shukri F. Khuri	STA-001CX	3828
207 7590 07/17/2009 WEINGARTEN, SCHURGIN, GAGNEBIN & LEBOVICI LLP TEN POST OFFICE SQUARE BOSTON, MA 02109				
EXAMINER NASSER, ROBERT L				
ART UNIT		PAPER NUMBER		
3735				
MAIL DATE		DELIVERY MODE		
07/17/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/628,866

Applicant(s)

KHURI ET AL.

Examiner

ROBERT L. NASSER

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-37 and 40-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-37 and 40-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-85/86)
Paper No(s)/Mail Date 6/23/2009
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Inventor's Patent Application
- 6) ☐ Other: _____

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/23/2009 has been entered.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 30-37 and 40-52 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 6567679. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are differently worded versions of the patented claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30, 32, 35-37, and 40-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Tantillo et al article entitled, "Myocardial tissue pH in the assessment of the extent of myocardial ischemia and the adequacy of myocardial protection in view of Abbott 5385540. Tantillo discloses throughout a method including measuring the pH of the heart. Then on pages 344 and 345, 347-349, it teaches recognizing suboptimal pH levels of the heart, and delivering cold cardioplegia to one of a plurality of possible sites (i.e. aortic root of left main coronary artery) in response to low pH levels. Tantillo shifts delivery from a needle in the aortic root to a catheter in the coronary sinus. As such, the delivery mechanism is a "system." In addition, Abbott teaches that it is known to treat a patient during bypass surgery with cardioplegia by varying the temperature and/or flow rate. Hence, it would have been obvious to modify Tantillo to vary the flow rate, to ensure that the patient gets proper treatment. Claim 35 is rejected in that if the delivery of cardioplegia is turned on and off, it is inherent that there is a valve. In addition, with respect to claim 36, it would have been obvious to alert the physician by displaying to any changes occurring in such an automated procedure, to provide the physician with full knowledge of the status. Claim 40 is

rejected in that Tantillo tests the pH of myocardial tissue. Claim 41 is rejected in that the examiner takes official notice that it is known to deliver electrodes to the heart via a delivery catheter. Hence, it would have been obvious to do so in Tantillo's method, as it is merely the substitution of one known delivery technique for another. Claim 42 is rejected in that In addition to the features of Tantillo discussed above, Abbott teaches that it is known to treat a patient during bypass surgery with cardioplegia by varying the temperature and/or flow rate. Hence, it would have been obvious to modify Tantillo to vary the temperature and flow rate, to ensure that the patient gets proper treatment. In addition, Tantillo already has the temperature sensor. Claim 42 is rejected in that Tantillo alters delivery of Cardioplegia based on temperature and pH. Claims 43-45 are rejected in that Abbott uses a controller to control temperature and flow rate of the cardioplegia. Hence, it would have been obvious to modify Tantillo to use such a controller, to eliminate human error. Claim 46 is rejected in that Tantillo alters the site of delivery. Claim 47 is rejected in that it is the examiner's position that there must be a valve to direct the flow. In addition, with respect to claim 48, it would have been obvious to alert the physician by displaying to any changes occurring in such an automated procedure, to provide the physician with full knowledge of the status. Claim 49 is rejected in that in order to control temperature and flow, data must be provided. Claim 50 is rejected in that the tissue is myocardial. Claim 51 is rejected in that the examiner takes official notice that it is known to deliver electrodes to the heart via a delivery catheter. Hence, it would have been obvious to do so in Tantillo's method, as it is merely the substitution of one known delivery technique for another. With respect to

claim 52, Tantillo has a first flow path to a catheter (in the aortic root) and a third flow path to a needle (in the coronary sinus). Tantillo further has a second delivery site (through the graft). It is the examiner's position that some sort of flow tube (cannula) is necessary to provide the cardioplegia at the graft. In addition, the examiner takes official notice that using a manifold is a known way to distribute fluid to multiple paths.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tantillo et al in view of Abbott, as applied to claims 30, 32, 35-37, and 40-52 above, further in view of Lee. Tantillo manually adjusts the delivery of the solution. Lee is selected from a myriad references that automates such a delivery, to remove human error. Hence, it would have been obvious to modify Tantillo to use a control, to increase the accuracy of the system and eliminate human error

Applicant's arguments filed 6/23/2009 have been fully considered but they are not persuasive.

Applicant has asserted that Tantillo does not have a system. The examiner disagrees. Tantillo has a catheter in the aortic root and a needle in the coronary sinus and a third delivery location. It is the examiner's position that this constitutes a system.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT L. NASSER whose telephone number is (571)272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner
Art Unit 3735

RLN
July 17, 2009